

REMARKS:

The preceding claim amendments and the following remarks are submitted as a full and complete response to the Office Action issued on August 8, 2007. Claims 1-2 have been amended to delete the non-elected subject matter and to recite that the first peptide is mammalian PLD and the second peptide is mammalian actin. Claim 2 has further specified that PLD is selected from PLD 1 or PLD2; and actin is selected from α -actin or β -actin. Support for these amendments can be found throughout the specification, for example, pages 1-2, paragraph 3; pages 7-8, paragraph 21, and Example 1. Claims 3 and 4 have been amended to recite that the first and second peptides contain a datable tag. Claims 6-13 have been amended to be directed to a process using the peptide complex as claimed in the amended claim 1. Since these claims are the process claims of the elected claims for product, they are entitled to be rejoined to this application once the elected product is found allowable. Applicants reserve the right to file a divisional application to prosecute the subject matter deleted by the current claim amendments.

Applicants respectfully request entry of these claim amendments and favorable reconsideration of the application.

I. Objection to Claims 1-5 and Sequence Listing

Claims 1-5 are objected to on grounds that they recite non-elected subject matter. The amendment of claims 1-5 to delete the non-elected subject matter renders this objection moot.

The Office states that Figure 3B, Figure 26A and page 35 of the specification present sequence, or sequence comparison or short sequences but the specification fails to comply with the requirements. Applicants would like to

bring to the Office's attention the previous submission of a sequence listing (both paper and computer readable copies) accompanied by the relevant amendments to the specification, which were filed on December 13, 2005. Thus, Applicants respectfully submit that this application meets the sequence listing requirements under 37 CFR 1.821-825 by the previous submission. Withdrawal of the objection is therefore warranted.

II. Rejections of Claims 1-5 under 35 U.S.C. §112, first para.

Written Description

The Office has rejected claims 1-5 for lack of written description. The Office argues that the inventors are not in possession of the claimed peptide complex comprising PLD and actin from any source. The Office also indicates that the specification lacks "any disclosure or description of the structure and function of all variant complex sequences having a defined function or activity." The Office further argues that the specification as filed does not describe specific assays to measure the various polypeptide complexes having the "PLD-actin activity." peptide complex. Applicants respectfully traverse this rejection.

At the outset, Applicants would like to draw the Office's attention to the amended claim 1, which specifies a source of PLD and actin as mammals. As the Office Action has admitted, the specification discloses the PLD-2-binding protein from rat brain obtained using the antibody to the rat PLD-2 (of sequence of SEQ ID No. 8) and the identification of rat brain β -actin (43-kDa protein). See page 6 of the Office Action. The specification teaches mammalian PLDs and actins. See e.g., pages 1-2, paragraph 3; pages 7-8, paragraph 21. The specification also contains an example (Example I) showing how to identify the peptide complex formed by

using the antibodies of rat PLD2 and rat actin.

Applicants respectfully submit that the disclosure of the specification relating to a peptide complex containing rat PLD and rat actin is sufficient to represent the claimed mammal PLDs and mammal actins. As shown in the attached publications, M.A. Frohman et al., Mammalian phospholipase D structure and regulation, Biochimica et Biophysica Acta, 1439, pp 175-186 (1999) ("Frohman") and J.H. Exton, Minireview: Regulation of phospholipase D, FEBS Letters, 531, pp. 58-61 (2002) ("Exton"), various mammalian PLDs were identified and sequenced before the effective filing date of this application. More importantly, the regions having catalytic function are conserved through different species. See page 176 of Frohman and page 58 of Exton

Similarly, actins from different species exhibit the high sequence conservation among different species. See E.S. Hennessey et al. Review Article: Molecular genetics of actin function, Biochem J., 282, pp 657-671 (1993) ("Hennessey"). With respect to mammalian actins, Hennessey teaches that "[s]keletal muscle α -actins in human, mouse, rat, rabbit and chicken are identical, as are the cytoplasmic β -actins in human, mouse, rat, cow and chicken." See page 657, right column.

Considering the known conserved regions for catalytic functions in mammalian PLDs and actins, one skilled in the art would understand that the activity or function shown in the peptide complex containing rat PLD and rat brain actin would be representative to the claimed peptide complexes containing mammal PLDS and mammal actins. Therefore, Applicants respectfully submit that unlike the Office's position, one skilled in the art would consider that the inventors' of this application were in possession of the claimed complex of the amended

claim 1.

Considering the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

Enablement

The Office has also rejected claims 1-5 as non-enabled. The Office argues that the specification "does not reasonably provide enablement for any peptide complex(s) comprising any phospholipase D (PLD) and actins from any source and including variants, fragments and fusion peptides comprising PLD and actin from any source with no defined structure or any assigned function to the variant complex." Applicants respectfully disagree.

As explained above, the amended claim 1 specifies a source of the first and second peptides as mammals. Their sequences and the regions that maintain their functions among various mammals are highly conserved. The regions of PLDs or actins responsible for catalytic function are also known.

Thus, one skilled in the art would readily conduct modification of PLDS or actins without affecting their activities. Given the well known knowledge and information available in the relevant field, one skilled in the art would have been able to practice the claimed invention without undue experimentation.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Rejection of Claims 1-5 under 35 U.S.C. §101 for lack of Utility

The Office further rejected claims 1-5 for lack of either a specific or substantial utility or well-established utility. The Office argues that the main utility of the peptide-complex is to carry out further research to identify the biological function and possible diseases associated with said function, which are not

considered to have substantial, real-world utility. Applicants respectfully disagree.

The specification of this application states that, the claimed complex would be useful for screening a modulator of an interaction between PLD and a PLD binding partner. The modulator, according to the specification, is useful in treating diseases and disorders such as neurodegenerative diseases, autoimmune diseases, cancer and diabetes. See page 2 at paragraphs 5, 6, 56-68. For example, PLDs are overly expressed in certain cancers and actins inhibit the activity of PLDS. See e.g., D-Y. Noh et al., Overexpression of phospholipase D1 in human breast cancer tissues, Cancer Letters, 161, pp 207-214 (2000). The claimed complex can be used to screen such a modulator that can control the interaction between PLD and actin or stabilizing the peptide complex. Then, the modulator can be used for treating certain cancers in which PLDs are overly expressed, such as breast cancer.

The utility of the claimed peptide complex, as described in the specification, is specific and substantial. An applicant's assertion of utility creates a presumption of utility that will sufficient to satisfy the utility requirement unless the examiner provides factual reasons which would lead one skilled in the art to question the asserted utility. The Office fails to recognize the utility described in the specification let alone provides any factual reasons to raise a doubt on the utility of the claimed peptide complex. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

In light of the foregoing, Applicants submit that all outstanding rejections have been overcome, and the instant application is in condition for allowance. Thus, Applicants respectfully request early allowance of the instant application.

The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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